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| APPLICATION NO.                    | FIL        | ING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|------------|------------|----------------------|---------------------|------------------|
| 09/899,526                         | 07/06/2001 |            | Royce Morrison       | 080382-0108         | 9915             |
| 22428                              | 7590       | 02/07/2006 |                      | EXAMINER            |                  |
| FOLEY AND LARDNER LLP<br>SUITE 500 |            |            |                      | CHOI, PETER H       |                  |
| 3000 K STREET NW                   |            |            |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20007               |            |            |                      | 3623                |                  |

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)                            |  |  |  |  |  |
|--|---|---|--|--|--|--|--|
|  | 09/899,526  | MORRISON, ROYCE                         |  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit                                |  |  |  |  |  |
|  | Peter Choi  | 3623                                    |  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c  | orrespondence address                   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |   |  |  |  |  |  |
| Status   |   |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 25 No.  | ovember 2005.   |   |  |  |  |  |  |
| ·— ·   | •   |   |  |  |  |  |  |
| 3) Since this application is in condition for allowan  |   | secution as to the merits is            |  |  |  |  |  |
| ,  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.     |   |  |  |  |  |  |
| Disposition of Claims  |   |   |  |  |  |  |  |
| 4)⊠ Claim(s) <u>8-11</u> is/are pending in the application.  |   |   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |   |  |  |  |  |  |
| 6)⊠ Claim(s) <u>8-11</u> is/are rejected.  |   |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  | <u></u>   |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | election requirement.   |   |  |  |  |  |  |
| Application Papers   |   |   |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |   |  |  |  |  |  |
| 10) ☐ The drawing(s) filed on <u>7/6/01</u> is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.   |   |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |   |  |  |  |  |  |
| , ·  |   | , |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |   |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:   | 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).       |   |  |  |  |  |  |
|  |   |   |  |  |  |  |  |
|  |   | on No                                   |  |  |  |  |  |
| <del></del>  | 2. Certified copies of the priority documents have been received in Application No                    |   |  |  |  |  |  |
|  | 3. Copies of the certified copies of the priority documents have been received in this National Stage |   |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |   |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |   |  |  |  |  |  |
|  |   |   |  |  |  |  |  |
| Attachment(s)  |   |   |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |   |   |  |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date  Notice of Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Notice of Informal Patent Application (PTO-152)   |   |   |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date   | 6) Other:   | atent Application (FTO-152)             |  |  |  |  |  |
|  |   |   |  |  |  |  |  |

Art Unit: 3623

#### **DETAILED ACTION**

1. The following is a **FINAL** office action upon examination of application number 09/899,526. Claims 8-11 are pending in the application and have been examined on the merits discussed below.

# Response to Amendment

2. Applicant's amendment filed 11/25/05 canceled claims 1-7, added new claims 8-11, and amended the specification and Figure 3.

### **Drawings**

- 3. The drawings were received on 11/25/05. These drawings are acceptable.
- 4. In view of Applicant's amendments to the specification and Figure 3 (submitted 11/25/05), previous drawing objections made under 37 CFR 1.84(p)(5) are withdrawn.

Application/Control Number: 09/899,526

Art Unit: 3623

## Response to Arguments

5. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

# Claim Rejections - 35 USC § 101

6. Previous rejections made under 35 USC § 101 are withdrawn.

# Claim Objections

- 7. Claim 10 is objected to because of the following informalities:
  - Limitation c) contains additional limitations iii) and iv), without citing limitations i) and ii)

The Examiner recommends replacing iii) and iv) with i) and ii). Appropriate correction is required.

### Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. The preamble of the claim cites, "A computer implemented <u>system</u> for marketing a health care product, the <u>method</u> comprising the steps of:" For purposes of examination, the Examiner has assumed that the preamble ought to read "A computer implemented method for marketing a health care product, the method comprising the steps of:"

A single claim having multiple statutory classes of invention is indefinite under 35 U.S.C 112, second paragraph. The second paragraph of 35 USC 112 requires a claim to particularly point out and distinctly claim the subject matter that the appellant regards as his invention. However, the "invention" referred to in the second paragraph of 35 USC 112 is also subject to the requirements of 35 USC 101. This section of the statute requires that in order to be patentable the invention must be a "new and useful process, machine, manufacture, *or* composition of matter, *or* any new and useful improvement thereof". A claim intended to embrace or overlap *two* different statutory classes of invention set forth in 35 USC 101 is precluded by the express language of 35 USC 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. A single claim which purposes to be both a product or machine and a process is ambiguous and is properly rejected under 35 USC 112, second paragraph, for failing to particularly point out and distinctly claim the invention. *Ex parte Lyell*, USPQ. 2d (Board of Aptent Appeals and Interferences) 1548, 1551.

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990)

10. Claim 8 recites the limitation "the computer system" in line 2 of limitation b). There is insufficient antecedent basis for this limitation in the claim. As stated above, the Examiner has assumed that claim 8 is a method claim. If claim 8 is actually a computer implemented system claim, no computer system has been positively recited within the body of the claims. The Examiner suggests that the limitation be rewritten as "retrieving stored information from a database accessible by <u>a</u> computer system, the stored information...".

### Claim Rejections - 35 USC § 103

11. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brinkman et al. (US Patent # 6,697,783) in view of Tallman et al. (US Patent #5,471,382).

As per claim 8, Brinkman et al. teaches a computer implemented method for marketing a health care product, the method comprising:

Art Unit: 3623

(a) receiving information about characteristics of at least one of a consumer (member profile 709, including areas that list the member's health benefit plan information, prescription drug history, self-reported health information, recent contact history, allergies 1501, prescriptions 1502, and pre-existing heath conditions 1503) and a decision influencer [Column 10, lines 22-29, Claim 1a];

- (b) based on the received information, retrieving stored information (clinical information 710) from a database accessible by a computer system, the stored information containing at least one of consumer information (recommended forms of treatment and courses of action), decision influencer information (health benefit information 712 such as insurance company rules, member information and benefit plan resources), and product information (recommended forms of medications, pharmaceutical information 711 such as prescription drug side effects and complications that may be associated with particular drugs or combinations of drugs) [Column 10, lines 30-47, Claim 1b, 1c, 1d];
- (c) analyzing the received information and the stored information to determine presence of a sufficient indication of:
  - (i) consumer interest in the health care product (request for a new prescription, prescription refill or prescription renewal; members who have called with inquiries about symptoms that can be treated by a new drug or treatment) [Claim 4, Column 11, lines 20-24, and Column 12, lines 45-47];
- (d) if sufficient indication is present, retrieving a list of potential actions (direct caller to an audiotext application 1110, select documents 1116 for the caller,

Art Unit: 3623

update member profile 1120 based on the inquiry made and advice given during the call, determine that a referral is necessary 1115) related to the health care product from a product information database [Column 15, lines 10-49];

- (e) evaluating whether to perform each of the potential actions (determine an appropriate course of action for the caller) based on at least one of the consumer information (member profile database 1121), the decision influencer information (clinical information database 1111, pharmaceutical information database 1112, and health benefit information database 113), the product information, and action-specific criteria [Column 14, line 62 Column 15, line 1]; and
- (f) performing potential actions (provide analysis and advice 708, transfer the caller to an appropriate operator in response to the caller's inquiry, generate a referral 1117 so that the caller may visit a participating provider; generate alerts and messages for the operator to provide to the caller relating to items such as appropriate prescription drug use, medications the caller should avoid or use in moderation or speak to a physician before using, suggested forms of treatment based on the caller's symptoms, prescription refill reminders, prescription renewal reminders, and other information; package information collected during the call, combined with specific pharmacy information, for delivery to the caller's physician, health plan, or other health care provider; direct the system to route the caller to an audio text application which contains pre-recorded messages on a number of frequently used health care topics; caller will be able to select a topic by a touch tone prompted menu, or the operator may select the topic for the

Page 8

caller) that meet action-specific criteria (system validates the caller's eligibility; determine that a referral is necessary 1115) [Column 10, lines 18-20, and Column 15, lines 10-49].

Brinkman et al. does not explicitly teach the step of using cost-effective criteria to evaluate whether to perform potential actions.

However, Tallman et al. teaches the step of evaluating potential actions (deciding on a course of action) using a cost-effective criteria by providing a patient assessment designed to prevent patients from seeing a doctor and receiving care that will not have medical benefit, and to prevent patients from receiving treatments from providers in areas other than their specialties, both of which result in higher costs incurred by the patient with no improvement [Column 6, lines 35-51]. Use of the patient assessment aims to avoid unnecessary (and costly) treatments from providers, thus employing a cost-benefit criterion when deciding on a course of action to recommend to patients.

Both Brinkman et al. and Tallman et al. are directed towards a telephonic system to assess, diagnose, and suggest treatment plans to appropriately care for patient illnesses. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the teachings of Brinkman et al. to include a cost-effective criteria when evaluating whether to perform a potential action, because the resulting

Application/Control Number: 09/899,526

Art Unit: 3623

combination would enable the patient to avoid unnecessary and costly treatment from unqualified providers that fail to yield any medical benefit.

As per claim 9, Brinkman et al. does not explicitly teach the method of claim 8 further including, prior to the performing step, prioritizing, sequencing and grouping the potential actions that meet the action-specific criteria.

Tallman et al. teaches the step of prioritizing the potential actions (Nurse Action List window presents a list of recommended actions to address the patient's condition. The possible actions are listed below in order of their medical priority: Activate Emergency Procedures, Speak to IAS Provider, Urgent Care, Transfer to Algorithm, Speak to Provider – Sorting, Speak to Provider – Treatment, Early Illness Appointment, Routine Illness Appointment, Self-Care; In the event that the NMS nurse reaches the end of an algorithm and the algorithm logic has made more than one recommended action, the NMS nurse will carry out the recommended action of the highest priority) [Column 23, line 44 – Column 24, line 11, Column 13, lines 26-33].

Tallman et al. teaches the step of sequencing potential actions (using Bayes

Theorem and yes-no branched chain algorithm logic to generate complaintspecific algorithms to determine by telephone the appropriate "next medical
step" for a caller; the algorithm logic lays out the questions in the order they will

Art Unit: 3623

be presented to the nurse by the system, representing branched chain logic, with the most sensitive questions being asked first, moving on, in response to positive answers, to more specific questions to identify more specifically timing and type of appropriate care; the formal structure of the NMS algorithm logic can designate that the NMS nurse either act on these action points as soon as they are reached or act on them "at the end of the algorithm") [Column 9, line 23 – Column 10, line 1, Column 11, line 57 – Column 12, line 3, Column 13, lines 26-33]

Tallman et al. teaches the step of grouping potential actions (each and every algorithm represents the best judgment of an experienced medical staff based on their cumulative experience and will serve as the baseline for evaluating the efficiency of the algorithm; The EVALUATE node types are designed for situations where an algorithm asks a series of related questions that are linked together as a set) [Column 11, lines 45-50, Column 59, lines 5-18]. Hence, the questions used by nurses (as laid out using the NMS algorithm logic) have been grouped together according to relevance.

Both Brinkman et al. and Tallman et al. are directed towards a telephonic system to assess, diagnose, and suggest treatment plans to appropriately care for patient illnesses. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the teachings of Brinkman et al. to include the step of prioritizing, sequencing and grouping the potential actions because the resulting combination would

Application/Control Number: 09/899,526

Art Unit: 3623

enable nurses to properly assess a patient for an appropriate timing and type of medical care that is best suited to address the needs of said patient.

Claim 11 recites similar limitations; therefore, the same rejection applies.

As per claim 10, Brinkman et al. teaches a computer implemented system for marketing a health care product, the method comprising:

- (a) means for receiving information (telephone voice line and computer 501) about characteristics of at least one of a consumer (system provides the operator with member profile 709, including areas that list the member's health benefit plan information, prescription drug history, self-reported health information, recent contact history, allergies 1501, prescriptions 1502, and pre-existing heath conditions 1503) and a decision influencer [Column 10, lines 22-29, Claim 1a; Column 8, lines 12-16];
- (b) based on the received information, means for retrieving stored information (system also provides the operator the ability to access databases that store clinical information 710) from a database accessible by the computer system, the stored information containing at least one of consumer information (recommended forms of treatment and courses of action), decision influencer information (health benefit information 712 such as insurance company rules, member information and benefit plan resources), and product information (recommended forms of medications, pharmaceutical information 711 such as prescription drug side

Art Unit: 3623

effects and complications that may be associated with particular drugs or combinations of drugs) [Column 10, lines 30-47, Claim 1b, 1c, 1d];

- (c) means for analyzing the received information and the stored information to determine presence of a sufficient indication of:
  - (i) consumer interest in the health care product (request for a new prescription, prescription refill or prescription renewal; members who have called with inquiries about symptoms that can be treated by a new drug or treatment) [Claim 4, Column 11, lines 20-24, and Column 12, lines 45-47];
- (d) if sufficient indication is present, means for retrieving (system may also allow the operator to order written materials 714 or orders for future delivery to the caller, the caller's health care provider, or a pharmacist) a list of potential actions (direct caller to an audiotext application 1110, select documents 1116 for the caller, update member profile 1120 based on the inquiry made and advice given during the call, determine that a referral is necessary 1115) related to the health care product from a product information database [Column 15, lines 10-49];
- (e) means for evaluating (operator's computer terminal is equipped with a screen or series of screens that detail and summarize the information loaded from the member profile database 1121, clinical information database 1111, pharmaceutical information database 1112, and health benefit information database 1113) whether to perform each of the potential actions (determine an appropriate course of action for the caller) based on at least one of the consumer information (member profile database 1121), the decision influencer information

Art Unit: 3623

(clinical information database 1111, pharmaceutical information database 1112, and health benefit information database 113), the product information, and action-specific criteria [Column 14, line 62 – Column 15, line 1]; and

means for performing potential actions (provide analysis and advice (f) 708, transfer the caller to an appropriate operator in response to the caller's inquiry, generate a referral 1117 so that the caller may visit a participating provider; generate alerts and messages for the operator to provide to the caller relating to items such as appropriate prescription drug use, medications the caller should avoid or use in moderation or speak to a physician before using, suggested forms of treatment based on the caller's symptoms, prescription refill reminders, prescription renewal reminders, and other information; package information collected during the call, combined with specific pharmacy information, for delivery to the caller's physician, health plan, or other health care provider; direct the system to route the caller to an audio text application which contains pre-recorded messages on a number of frequently used health care topics; caller will be able to select a topic by a touch tone prompted menu, or the operator may select the topic for the caller) that meet action-specific criteria (system validates the caller's eligibility; determine that a referral is necessary 1115) [Column 10, lines 18-20, and Column 15, lines 10-49].

Brinkman et al. does not explicitly teach the step of using cost-effective criteria to evaluate whether to perform potential actions.

Art Unit: 3623

However, Tallman et al. teaches the step of evaluating potential actions (deciding on a course of action) using a cost-effective criteria by providing a patient assessment designed to prevent patients from seeing a doctor and receiving care that will not have medical benefit, and to prevent patients from receiving treatments from providers in areas other than their specialties, both of which result in higher costs incurred by the patient with no improvement [Column 6, lines 35-51]. Use of the patient assessment aims to avoid unnecessary (and costly) treatments from providers, thus employing a cost-benefit criterion when deciding on a course of action to recommend to patients.

Both Brinkman et al. and Tallman et al. are directed towards a telephonic system to assess, diagnose, and suggest treatment plans to appropriately care for patient illnesses. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the teachings of Brinkman et al. to include a cost-effective criteria when evaluating whether to perform a potential action, because the resulting combination would enable the patient to avoid unnecessary and costly treatment from unqualified providers that fail to yield any medical benefit.

Art Unit: 3623

#### Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Choi whose telephone number is (571) 272 6971. The examiner can normally be reached on M-F 8-5.

Art Unit: 3623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tariq Hafiz can be reached on (571) 272-6729. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PC

February 1, 2006

Peter Choi Examiner Art Unit 3623

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3000